

PATENT
USSN 09/990,080
Docket 018/258c

REMARKS

This paper is responsive to the Office Action dated October 17, 2005, which is the third non-final action on the merits of the application.

Claims 1-7, and 9-22 were previously pending in the application, with claims 18-20 and 22 withdrawn from examination. Claims 1 and 10 are *allowed*, for which applicant is grateful.

Upon entry of this amendment, certain claims are cancelled and amended, and claims 23-28 are newly added. Claims 23, 24, 26, and 27 mirror claims 10 and 12, except that they depend from other product claims, and fall within the group elected for examination. Claim 25 and 28 mirror claim 22, which is withdrawn from examination. Accordingly, claims 1, 4, 5, 10, 12, and 22-28 are pending, with claims 1, 4, 5, 10, 12, 23, 24, 26, and 27 under examination.

Applicant acknowledges with gratitude withdrawal of rejections under 35 USC § 112 ¶ 1 respecting claims 1, 4, 5, and 10; and under § 112 ¶ 2 respecting claims 1-3, 5-7, 16, and 17.

Further consideration and allowance of the application is respectfully requested.

Interview Summary:

The undersigned wishes to express his gratitude to Examiner Malgorzata Walicka and Examiner Rebecca Prouty for the helpful and constructive interview held by telephone on December 13, 2005. The undersigned also wishes to thank Examiner Walicka for helpful follow-up discussions by telephone. Amendments and remarks discussed during the interviews are incorporated into this response.

Amendment to the specification:

The undersigned has discovered a part of the specification of the parent application (now U.S. Patent 6,337,200) that was inadvertently left out of this continuation. The parent application is incorporated into this application by reference on page 1, lines 6-11 of the specification as filed.

Accordingly, no new matter is added to the disclosure as a result of entering this amendment.

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Rejections:

Claims 2, 3, 6, and 7 stand rejected under § 112 ¶ 1 for containing new matter. The Office Action supposes that since this application does not claim priority to USSN 08/974,549, which later issued as U.S. Patent 6,168,178, it does not describe the use of the claimed variants for producing antibody.

Applicant respectfully disagrees. It is not necessary for an application to claim priority to an earlier disclosure in order to incorporate it by reference. Dr. Morin is a named inventor on both the present application for hTERT variants, and the issued patent for the naturally occurring hTERT sequence. The skilled reader will understand that the inventor possessed the use of variants of hTERT for making antibody, since the '178 patent contemplates the making of antibody with any fragment or variant of hTERT that includes at least one immunogenic epitope. The inactive variants claimed here are certainly long enough to include at least one immunogenic epitope of hTERT, and have the further advantage that they will not have the incidental side-effect of increasing telomerase activity in the immunized host.

Since these inactive variants are a very specialized and empirically determined subset of hTERT described in the '178 application, their suitability for making antibodies is apparent. Direct evidence that the inventor had possession of the use of the variants of this invention with antibody comes from the application as filed with reference to epitopes on page 5, lines 1-10 of the substitute specification, and reference to immunoprecipitation on page 8, lines 13-26.

Nevertheless, claims 2, 3, 6, and 7 have been cancelled in this amendment without prejudice to advance prosecution of the application, since important commercial embodiments of the inactive variants are adequately covered in the other claims. Applicant retains the right to reintroduce claims to the cancelled subject matter in this or a related application at a later time.

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Claims 9, 11, 12, 13-17, and 21 stand rejected under 35 USC § 112 ¶ 1 as not being enabled by the specification, on the basis that the specification does not provide sufficient structural characteristics for what is claimed. Claim 13 and its dependents stand rejected under § 112 ¶ 6 on the basis that the specification does not disclose identifying characteristics for structures that inhibit telomerase. Claim 13 also stands rejected under 35 USC § 102(e) as anticipated by U.S. Patent 6,842,662.

Applicant respectfully disagrees. Structures falling within claims 13 and its dependents are precisely indicated in the specification. The skilled reader will be able to identify equivalents based on a structural comparison with the disclosed embodiments and a test of functional activity. This is all that § 112 ¶ 6 (and hence § 112 ¶ 1) requires.

Nevertheless, claims invoking § 112 ¶ 6 and explicitly referring to polynucleotide mimetics have now been cancelled without prejudice. Applicant retains the right to reintroduce claims to the cancelled subject matter in this or a related application at a later time.

Claims 2, 3, 4-7, and 12 stand rejected under 35 USC § 112 ¶ 1 as lacking sufficient written description. Claims 3, 5, 16, and 17 stand rejected under § 112 ¶ 2 on the basis that it is unknown which amino acids are included and excluded.

Applicant respectfully submit that the amendments indicated above overcome all these issues.

Specifically, claims 2, 3, 6, 7, 16, and 17 have now been cancelled. Claim 12 has been amended to depend from claim 1 rather than claim 2. Claim 5 has been amended to incorporate the functional language of claim 1, as discussed during the interview. Accordingly, it is patentable in the same manner as claim 1.

Claim 4 is a more straightforward analysis, since structures referred to are narrower than those in claim 1 or claim 5. The deletions must include *at least* 10 consecutive amino acids of a region identified in the specification as being critical for telomerase function (Table 1, page 8). Thus, the specification describes and the reader will be able to find telomerase variants that *lack telomerase activity*, as required by the claim, within the required parameters. The claim also indicates that the protein is *otherwise a full-length telomerase*, defining the structure acceding to the deletion referred to, in the context of the native full-length sequence.

Since the claimed variant lacks telomerase activity, the skilled reader will appreciate that the variant has various uses, such as for inhibiting telomerase activity as a dominant-negative mutant, for raising antibody, and for acting as a control protein in assays for telomerase activity (page 4, lines 5-12 of the substitute specification) or screening (page 4, lines 1-2).

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Accordingly, the specification fully describes and enables the narrow range of inactive variants of hTERT covered by claim 5, and there is no need to further constrain the species according to a particular functional activity, as in claim 1.

Withdrawal of all these rejections is respectfully requested.

Request for Rejoinder:

Withdrawn claims 22, 25, and 28 are method claims that depend from and incorporate the limitations of product claims 1, 4, and 5 in the elected group. Production of hTERT variant proteins by expressing a polynucleotide that encodes the protein is disclosed *inter alia* on page 7, lines 15-19.

Accordingly, applicant hereby requests that these claims be rejoined into the application, upon determination that the product claims are patentable, in accordance with MPEP § 821.04.

Request for Interview

Applicant respectfully requests that all outstanding rejections be reconsidered and withdrawn. The application is believed to be in condition for allowance, and a prompt Notice of Allowance is requested.

In the event that the Examiner determines that there are other matters to be addressed, applicant hereby requests an interview by telephone.

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Fees Due

No fee is believed payable for entry and consideration of these amendments and remarks.

Nevertheless, should the Patent Office determine that a further extension of time or any other relief is required for further consideration of this application, applicant hereby petitions for such relief, and authorizes the Commissioner to charge the cost of such petitions and other fees due in connection with the filing of these papers to Deposit Account No. 07-1139, referencing the docket number indicated above.

Respectfully submitted,

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